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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/826,463 | 04/05/2001 | Nobuto Yamamoto | Y1004/20017 | 2419 |

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EXAMINER

ROMEO, DAVID S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,463

Applicant(s)

YAMAMOTO, NOBUTO

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The amendment filed February 28, 2002 (Paper No. 4) has been entered. Claims 21-23 are pending.

Applicant's election with traverse of group I in Paper No. 4 is acknowledged. The traversal is on the ground(s) that claim 23 depends from claim 21 and thus a search of group I requires a search of XVIII. This is not found persuasive, firstly, because claim 23 is directed to a process of using a product made by the process of claim 21. The process of claim 21 is not viewed as positively limiting the product produced by claim 21 absent a showing that the process imparts a novel or unexpected property to the product, as it is assumed that equivalent products are obtainable by multiple routes. Secondly, claim 23 recites "a cloned macrophage activating factor (GcMAFc) made in accordance with the process of claim 1" and the process of claim 21 does not make a cloned GcMAFc. Thirdly, the recitation of "a cloned macrophage activating factor (GcMAFc) made in accordance with the process of claim 1" occurs in the preamble of claim 23 and the intended use must result in a manipulative difference as compared to the prior art. The intended use of the claimed method does not distinguish the claimed method from Yamamoto's (a5) method. The intended use does not result in a manipulative difference as compared to the prior art. The intended use has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process and the body of the claim does not depend on the preamble for completeness but, instead, the process steps are able to stand alone. Fourthly, all that claimed 23 requires is "contacting cloned Gc protein." The limitation "cloned Gc protein" is

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viewed as a product-by-process limitation and the cloning process is not viewed as positively limiting the Gc protein product produced by the cloning process absent a showing that the process imparts a novel or unexpected property to the product, as it is assumed that equivalent products are obtainable by multiple routes.

The requirement is still deemed proper and is therefore made FINAL.

Claim 21 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

Claims 22, 23 are being examined.

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. See Figure 6. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used

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to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Applicant may bring the figure(s) into compliance by amending either the figure(s) or the "Brief Description of the Drawings" to recite the appropriate sequence identifier.

Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto (a5) in view of Cooke (u5).

Yamamoto teaches a process of converting glycosylated Gc protein to a highly potent macrophage activating factor (GcMAF) by contacting Gc protein with immobilized β -galactosidase and sialidase (Example 2, columns 9-10). The Gc protein has a molecular weight of about 52,000 (sentence bridging columns 1-2) and comprises approximately 458 amino acids, as indicated in Figures 1 and 2. The Gc protein has a molecular weight of about 52,000, comprises approximately 458 amino acids, and has three distinct domains, as taught by Cooke (Figure 3; page 2423, paragraph bridging left and right columns). Yamamoto also discloses GcMAF comprises a protein having the amino acid sequence of Gc protein and an N-

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acetylgalactosamine group linked to amino acid residues 420 and/or 418 via an O-glycosidic linkage (column 5, lines 27-40). The limitation "cloned Gc protein" is viewed as a product-by-process limitation and the cloning process is not viewed as positively limiting the Gc protein product produced by the cloning process absent a showing that the process imparts a novel or unexpected property to the product, as it is assumed that equivalent products are obtainable by multiple routes.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is indefinite because line 2 is grammatically incorrect thereby rendering the metes and bounds of the claimed invention ambiguous. See the phrase "Gc protein a molecular weight" in line 2. The metes and bounds are not clearly set forth.

Claim 23 is indefinite since it depends from a canceled claim (claim 1), and thus makes no sense, since it is incomplete. In the interest of compact prosecution the claim will be interpreted as incorporating the limitations of claim 21. However, this interpretation of the claim does not relieve applicant from the requirement to respond to the instant rejection.

Claim 23 is indefinite because it recites "a cloned macrophage activating factor (GcMAFc) made in accordance with the process of claim 1" and the process of claim 21 does not

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make a cloned GcMAFc. It is also unclear what process(es) is encompassed by the phrase "made in accordance with." The metes and bounds are not clearly set forth.

Claim Objections

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A "cloned macrophage activating factor (GcMAFc) made in accordance with the process of claim 1" (claim 23) fails to further limit the process of claim 21 because the process of claim 21 does not make a cloned GcMAFc.

Conclusion

No claims are allowable. Claims of a scope similar to the present claims were rejected under 35 U.S.C. 103(a) in Applicant's predecessor application U.S. application serial no. 08/618,485 and that rejection was affirmed after appeal before the board of patent appeals and interferences.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MAY 6, 2003